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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/767,642	STEINMANN, SCOTT P.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-10 and 27-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-10 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 2, and 4-10 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that both Rauscher (US 6,887,277 B2) and Masini (US 6,821,300 B2) do not disclose a head with a concavity adapted to contact another bone. The examiner disagrees. Rauscher discloses concavity (19) and Masini discloses concavity on the inner surface of head (330). Each concavity is adapted to contact another bone, since the claim does not require the head to be secured to the stem when the concavity has to contact another bone. Therefore, since the heads need not be secured to the stems at this time, they may be moved to different positions or locations and are "adapted to contact another bone". If applicant were to claim "when the head of the prosthesis is secured to the stem" as recited in claims 27 and 31, with the concavity limitation, these rejections would be overcome.

A new rejection has been made on the previously indicated allowable claims, therefore this action is non-final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-10 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8, 27, and 31 each recite the limitation "each opening" in lines 10 and 14 of claim 1, lines 11 and 15 of claim 8, lines 9 and 13 of claim 27, and lines 10 and 14 of claim 31. There is insufficient antecedent basis for this limitation in the claims. It is suggested to change the above to "each at least one opening" or "the at least one opening". Claims 2, 4-7, 9-10, 28-30 and 32-33 depend upon the above claims and inherit all problems with them.

Claims 1, 8, 27, and 31 recite the limitation "at least one opening" in lines 15, 16, 14 and 15 respectively. There is insufficient antecedent basis for this limitation in the claims. It is unclear if this limitation is referring to the previously recited "at least one opening" or it is referencing a new or additional opening.

Claims 1, 8, 27, and 31 recite the limitation "at least one screw" in lines 19, 20, 18, and 19 respectively. There is insufficient antecedent basis for this limitation in the claims. It is unclear if applicant is referring to one of the previously recited "screw" or a new or additional screw.

Claims 4, 29, and 33 each recite the limitation "the openings" in line 2. There is insufficient antecedent basis for this limitation in the claims. It is unclear if applicant is referring to the "at least one opening" or the "three openings". The three openings are claimed to be additional openings. If this is not the intention, it is suggested to change the claim to recite, "wherein the at least one opening comprises three openings, and two of the three openings are".

Claims 4, 29, and 33 each recite the limitation "the wall" in line 3. There is insufficient antecedent basis for this limitation in the claims. It is suggested to change the above to "the outer wall".

Claim Rejections - 35 USC § 101

Claims 6, 7, 9, 10, and 27-33 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 6, 9, 27, and 31 each recite, "prosthesis replaces a radial head", which positively recites a portion of the body. It is suggested to change the above to recite, "prosthesis is adapted to replace a radial head".

Claims 7, 10, 28-30 and 32-33 depend upon the claims and inherit all problems associated with them.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-6, and 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Rauscher et al. (US 6,887,277 B2, cited previously). Rauscher discloses a prosthesis (see fig.11) comprising a stem (5+35), a head (33) having an outer wall (thickness of head) defining an interior space (19), wherein the head (33) may be placed over the stem end (35; over in its broadest plain meaning is defined as above; therefore when "over" it need not be secured on the stem, thus is capable of more movement if above the stem in space) adapted for transverse and axial movement (flexible head is compressible, allowing movement in multiple directions even when surrounding the stem end), the outer wall of the head having *at least one* opening (see fig.11), the outer wall of the head including a concave surface dimensioned to interface with another bone (inner concavity 19 is capable of contacting another bone; *it is noted that the claim*

does not require the head to be secured to the stem at this time, therefore the concavity 19 may be moved to contact another bone, it has the capability before securement), a screw (34) arranged in each opening adapted to contact the end of the stem and secure the head by constraining axial and transverse movement (see fig.11; col.4, lines 60-65), wherein each opening is in a lateral direction to the stem axis (seen in fig.11 as perpendicular to the stems longitudinal axis) and an interior surface of the head wall adjacent the aperture is spaced from and end of the stem (adjacent aperture is spaced axially from the stem head; adjacent aperture is spaced radially also, inherently since relative movement occurs prior to securement by screw in order to orient and fix in the correct position; col.4, lines 60-65; also one can not assume that the figures are to scale), and wherein the screw contacts a side surface of the end of the stem (see fig.11). Rauscher's prosthesis replaces a bone having a head with a radial dimension (radial head) thus meets the claim. If applicant intends to claim the actual radius bone, it is suggested to change the above to "the radial head of the radius" or "the head of the radius bone".

Claims 1, 2, 4-6, and 8-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Masini (US 6,821,300 B2, cited previously). Masini discloses a prosthesis (see fig.3-6) comprising a stem (310), a head (330) having an outer wall (thickness) defining an interior space, wherein the head (330) may be placed over the stem end (310) adapted for transverse and axial movement, the outer wall of the head having *at least one* opening (three or more openings, see fig.3), the outer wall of the head including a concave surface (surface facing the bone in figs) dimensioned to interface with another bone (inner concavity is capable of contacting another bone; *it is noted that the claim does not require the head to be secured to the stem at this time,*

therefore the concavity may be moved to contact another bone, it has the capability before securement to the stem), a screw (332) arranged in each opening *adapted* to contact the end of the stem (screws are capable of being threaded to contact the stem) and secure the head by constraining axial and transverse movement, wherein each opening is in a lateral direction to the stem axis (seen in fig.3) and an interior surface of the head wall adjacent the aperture is spaced from and end of the stem (fig.3,4, 5), and wherein the screw (332) contacts a side surface of the end of the stem (adapted to be threaded more to contact the stem through the bone. Masini's prosthesis replaces a bone having a head with a radial dimension (radial head) thus meets the claim. If applicant intends to claim the actual radius bone, it is suggested to change the above to "the radial head of the radius" or "the head of the radius bone" or something along these lines.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rauscher et al. (US 6,887,277 B2, cited previously). Rauscher discloses a prosthesis having a stem and head adapted to be secured onto the stem by an opening/screw connection (see above). Rauscher however discloses only one opening/screw (34 in fig.11) instead of three as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have three openings instead of three, since the result would be merely further security and a duplication of the original parts. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Claims 1, 2, 4-6, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (US 2002/0055744 A1, cited previously). See figures 14, 15 and respective portions of the specification. Reiley discloses a prosthesis comprising a stem (110), a head (131+160) having an outer wall (131) having an interior space (bottom surface) such that the head (131+160) may be placed over the end of a stem (see figs.14, 15), the outer wall having an opening (three openings, two for screws 133 and one for connector 115a), the outer wall dimensioned to move in an axial direction and transverse direction relative the stem when the head is placed over the stem ("over" can mean above, lying above the stem in space as it is prior to attachment; alternately upon placement it is also moved axially down connector 115a, and may rotate, thus capable of transverse movement also prior to securement), the outer wall of the head (outside of 160) having a surface to interface with another bone, a screw (133a, 133b, seen in figs.14, 15) for arrangement in the openings and for contacting the stem for securement, the openings being lateral to the stem axis (see figs.14, 15), the interior surface of the head (bottom surface) spaced from the stem end (see figs), the screw contacting the side of the stem end when secured (see figures). Reiley discloses the prosthesis substantially as claimed, however discloses the head to have an outer convex surface instead of a concave surface. Since Reiley has shown in figure 15, the convex surface mating with an opposite concave surface, with the same connections means to the stem, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reverse the parts so that the concave surface is the lower articulating component instead of the upper articulating component and vise versa for the convex surface. *In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955).

Claims 1, 2, 4-10, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 6,656,225 B2, cited in IDS). Referring to claims 1, 2, 5-10, 27, 28, and 30-32, Martin discloses a prosthesis (fig.9, 10) comprising a stem (10), a head (30) having an outer wall (32) that can be placed over the end of the stem (10; yes 30 is capable of fitting over 10) the outer wall having at least one opening (Martin discloses alternate securement means to the protuberances, such as a screw connection to stem, which would inherently be placed through an opening; col.9, lines 19-25), the wall being dimensioned to be capable of movement in an axial direction and transverse direction relative to the stem axis (part 30 is capable of movement with respect to part 10-part 20 need not be present since claims have term "comprising", however even if part 20 is present, part 30 can move axially down on part 20 and rotationally, thus transversely), the outer wall (32) including a concave surface (37) for interfacing with another bone such as the capitellum of the humerus, the wall (32) having a periphery (side) that is capable of mating with the ulna; and a screw (alternate connection; col.9, lines 19-25) adapted for contacting the stem end, the prosthesis for replacement of the head of a radius (col.1, lines 5-15) and being elliptical (Martin's head is cylindrical, having a circular cross section or plan view; a circle is an ellipse; an ellipse is defined as a curve having two foci, however when the two foci coincide or are equal, the ellipse is a circle; thus Martin's circle reads on the ellipse claimed). Martin discloses the prosthesis substantially as claimed, having a stem, head and screw for securing the head to the stem, however, Martin is silent to mention or show the location of the screw connection (it is claimed to contact the side of the stem). It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the screw at the side surface of the head (and stem) since the head has only a side periphery surface and a top

articulating surface and one having ordinary skill in the art would not want to place a screw on the top articulating surface since this structure would interfere with articulation and additionally form debris, therefore the only obvious alternative placement would be on the side surface of the head to screw into the stem.

Referring to claims 4, 29, and 33, Martin discloses a prosthesis having a stem and head adapted to be secured onto the stem by an opening/screw connection (see above). Although Martin mentions the use of a screw to secure the head to the stem through an opening (col.9, lines 19-25), Martin does not disclose a particular number of screws/openings (such as three claimed). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have three screw openings, since the result would be merely further security and a duplication of the original parts. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CM/

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